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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined. ☒ Responsive to communication filed on October 12,1995 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire THREE (3) month(s), --- days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claim(s) 1-44 are pending in the application.
   Of the above, claim(s) _____ is withdrawn from consideration.
2. ☐ Claim(s) _____ has been canceled.
3. ☐ Claim(s) _____ is allowed.
4. ☒ Claim(s) 1-44 are rejected.
5. ☐ Claim(s) _____ is objected to.
6. ☐ Claim(s) _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawing(s) under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawing(s) are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction(s), filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under 35 USC 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

112 OBJECTION, REJECTION; FIRST PARAGRAPH

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention failing to adequately teach how to make and/or use the invention fairly responding an enabling disclosure (see item F below). The specification, as originally filed, does not provide support for the invention as is now claimed. (See items A-K below).

The original specification, claims and drawings are silent as to the following items:

A) Page 9, line 25 the insert after--wavelengths--; "six wavelengths in an absorbance set".

B) Page 9, line 32 the insert after --wavelength--; "forms a scattering subset".

C) The insert of page 10, line 24+ of the Amendment of Oct. 12, 1995 of page 3 lines 8-9; "the detecting step may be performed over a cone of radiation with a half-angle"

The original specification; claims and drawings recite nothing about a cone of radiation and recite a half-aperture angle.

D) The insertion of page 10, line 24+ of the Amendment of Oct. 12, 1995 of page 5 lines 14-17; "the method also contemplates simultaneously correcting the calculated .. scattering". The original specification, claims and drawings are silent as to simultaneous correction.

E) Page 16, line 15 insert after --measuring-- (second occurrence); "an absorbance subset of"

F) Page 20, line 29 insert after --compensated--; In other words .. K.. n-k .. wavelengths".

Also how can there be n-k wavelengths when K represents constituent components. What is meant by n-k wavelengths in a scattering subset of wavelengths?

G) Page 23, line 27 insert after --wavelengths--; "In embodiment A ... In Embodiment B ... subset".

H) Page 34, line 18 "five".

I) Page 35, line 7 insert after --br--; "Thus Embodiment C .. six.. two wavelength"

J) In new claim 37:

I) K of said no wavelengths ... components

II) n-k of said n wavelengths ... selected .. blood.

K) In new claim 38:

I) K absorbance vectors in said linear combination being equal to said concentrations of said K constituent components.

To clarify the items A-B, E-J above; the original specification, claims and drawings are silent as to the selection of which wavelengths are the absorption set and which wavelengths are the scattering set as now cited in the amendment of 10/12/95, but not the general phraseology that of the plurality of wavelengths some are of an absorbance set, same of a scattering set as cited in the original claim 1.

Claims 37-44 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

AMENDMENT OBJECTED; 35 USC 132

The amendment filed Oct. 12, 1995 is objected to under 35 U.S.C. § 132 because it introduces new matter into the specification. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: See section above.

Applicant is required to cancel the new matter in the response to this Office action.

112 REJECTION; SECOND PARAGRAPH

Claims 1-44 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

I)Claim 1 is unclear.

Lines 3-7 recite the following:

A) each wavelength of an absorbance subset of said plurality of wavelengths selected to minimize the effects of radiation scattering.

Lines 7-9 recite the following:

B) each wavelength of a scattering subset of said plurality of wavelengths having been selected to maximize the effects of radiation scattering.

Lines 11-13 recite the following:

C) irradiating a sample of unaltered whole blood of unknown composition with said plurality of radiation wavelengths through a depth of said sample to minimize radiation scattering by unaltered whole blood.

Lines 14-17 recite the following:

D) detecting intensities of said radiation wavelengths after passing through said depth of said sample at a distance from said sample and over a detecting area, both chosen to minimize the effects of radiation scattering.

Claim 1 contradicts itself and creates inconsistencies in that lines 3-7 recite to minimize the effects of radiation scattering, lines 7-9 recite to maximize the effects of radiation scattering, lines 11-13 recite to minimize radiation scattering and lines 14-17 recite to minimize the effects of radiation scattering.

From the specification, it appears that the main purpose of Applicant's device is to minimize the effects of radiation scattering (see page 14, lines 27-34. Also, see page 15, lines 25-31). Therefore lines 7-9 make no sense. Why would the wavelength be selected to maximize the effects of radiation scattering when the specification and lines 3-7, 11-13, and 14-17 recite that the wavelengths are selected to minimize the radiation scattering? What is Applicant claiming?

II. Claim 37 is unclear.

A) Line 6; what is meant by K of said n wavelengths? How can K be of said n wavelengths when K is defined as K constituent components of unaltered whole blood in line 2?

B) Line 8; what is meant by n-k of said n wavelengths? How can n-k be of said n wavelengths when k is k constituent components of unaltered whole blood in line 2? What is meant n-k? n minus K? n to k?

C) Line 9-10; What is meant by n-k scattering factors?

What causes the scattering factors? What does n-k mean?

D) Line 16-17; Is this correction for effects of radiation scattering related to the n-k scattering factors of lines 8-9? How are the K constituent components corrected?

II) Claim 38 is unclear.

A) Lines 2, 8; is this n the same n as in claim 37 from which claim 38 depends? a different n?

If not the same representation for different items should not be used. These questions also apply to should not be used line 7 of claim 38; n linear equations.

B) lines 9-10; Is this k the same k as in claim 37 from which claim 38 depends; k light absorbance vectors.

C) line 9; Is n-k the same n-k of claim 37?

What is meant by n-k?

D) lines 10-12; How can the real coefficient of said k absorbance vectors be equal to the concentrations of the k constituent components? How can coefficients of vectors be equal to concentrations? What is Applicant claiming?

F) Line 10, How are the real coefficients found? How are they related to the optical densities? the scattering factors? the absorbance vectors etc.?

III) Claim 39 is unclear.

A) line 3; What entries is Applicant referring to? Entries to what?

B) Is K of line 1 the same K of line 2? If not then a different representative for different items should be made.

IV) Claim 40 is unclear.

A) line 1; what does n-k mean? Is this the same n-k of claim 38 or different n-k? If not different representatives should be made.

The following lack antecedent basis:

Claim 39, line 5; "said n wavelengths".

Claim 41, lines 3-4; "n substantially monochromatic wavelengths"; Lines 5-6, "the extinction coefficients".

Claim 44, line 3 and 6; "the particular composition of the unalter whole blood."

REJECTIONS

Four different rejections, have been made, i.e. titled Rejection I, Rejection II, Rejection III, Rejection IV. Rejection I pertains to Anderson et al having the components of Applicant's claimed device and having the claims of the instant Application being different from the claims of 07/313,911.

Rejection II pertains to Anderson et al having the components of Applicant's claimed device and the claims of the instant application being the same as 07/313,911. Therefore, Res Judicata still stands.

Rejection III pertains to the Examiner's interpretation as to Applicant's true meaning of the subset phraseology argument and having the claims of the instant application being different from the claims of 07/313,911.

Rejection IV pertains to the Examiner's interpretation as to Applicant's true meaning of the subset phraseology argument and

having the claims of the instant application being the same as 07/313,911 (Thus Res Judicata).

REJECTION I

102 REJECTION

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10, 20-24, 26-27, 34-36, 37, 41, 43 (as understood by Examiner) are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Anderson et al.

Anderson specifically states in the abstract that the present study was made with an integrating sphere spectrometer (see fig. 1) and application of Twersky's theory for the multiple scattering of waves permitted separation of the effects of absorption and scattering and the light transmittance on nonhaemoglobin blood i.e. unaltered whole blood. It is shown

that the relationship between light scattering and red-cell concentration is parabolic and that the absorption of light with the erythrocyte is the same as in a haemoglobin solution, i.e. altered whole blood. See pages 174-183 in regard to the molar extinction coefficients, and the plurality of substantially monochromatic wavelengths. Note that Anderson inherently has correction for calculated concentrations, since the results of Anderson would have no meaning without such a correction. (See page 180, last line of the first paragraph).

103 REJECTION

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 2-9, 11-19, 25, 28-33, 38-40, 42, 44 (as understood by Examiner) are rejected under 35 U.S.C. § 103 as being unpatentable over Anderson et al.

Anderson in an unaltered whole blood measurement system, fails to disclose the specific depth of the sample, the specific detecting area, the specific distance from the sample, the specific half aperture angle of radiation emanating from the sample, computing an error index, selecting a wavelength range for bilirubin or sulfhemoglobin, red blood cell scattering vector and non specific scattering vector.

At the time the invention was made, it would have been obvious to one with ordinary skill in the art to modify Anderson to incorporate the specifics cited above. The rationale for this modification would have arisen, since it is apparent that the depth of the sample, the detecting area, the distance from the sample, and the half aperture angle all have a specific effect on the overall-measurement and it is a matter of design engineering to select which depth, area distance, or angle is required for a particular outcome. Anderson specifically shows that for different depths, different wavelengths etc., different results occur. Thus, a specific relationship between all of the specifics cited above are well known and it is up to the person conducting the measurement what specifies are required for that specific outcome to occur. As for the error index, bilirubin, sulfhemoglobin, red blood cell scattering and non specific

scattering vectors, the same reasoning cited above applies. It is up to the person conducting the measurement, as to what specifics are required for that specific outcome to occur.

In regard to claims 12-15, see page 177, second to last line of the first paragraph.

REJECTION II

102 REJECTION

Claims 1, 10, 20-24, 26-27, and 34-36, 37, 41, 43 (as understood by Examiner) are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by clearly anticipated by Anderson et al.

Anderson specifically states in the abstract that the present study was made with an integrating sphere spectrometer (see fig. 1) and application of Twersky's theory for the multiple scattering of waves permitted separation of the effects of absorption and scattering and the light transmittance on nonhaemoglobin blood i.e. unaltered whole blood. It is shown that the relationship between light scattering and red-cell concentration is parabolic and that the absorption of light within the erythrocyte is the same as in a haemoglobin solution, i.e. altered whole blood. See pages 174-183 in regard to the molar extinction coefficients, and the plurality of substantially

monochromatic wavelengths. Note that Anderson inherently has correction for calculated concentrations, since the results of Anderson would have no meaning without such a correction. (See page 180, last line of the first paragraph).

103 REJECTION

Claims 2-9, 11-19, 25 and 28-33, 38-40, 42, 44 (as understood by Examiner) are rejected under 35 U.S.C. § 103 as being unpatentable over Anderson.

Anderson in an unaltered whole blood measurement system, fails to disclose the specific depth of the sample, the specific detecting area, the specific distance from the sample, the specific half aperture angle of radiation emanating from the sample, computing an error index, selecting a wavelength range for bilirubin or sulfhemoglobin, red blood cell scattering vector and non specific scattering vector.

At the time invention was made, it would have been obvious to one with ordinary skill in the art to modify Anderson to incorporate the specifics cited above. The rationale for this modification would have arisen, since it is apparent that the depth of the sample, the detecting area, the distance from the sample, and the half aperture angle all have a specific effect on the overall-measurement and it is a matter of design engineering to select which depth, area distance, or angle is required for a

particular outcome. Anderson specifically shows that for different depths, different wavelengths etc., different results occur. Thus, a specific relationship between all of the specifics cited above are well known and it is up to the person conducting the measurements what specifies are required for the specific outcome to occur. As for the error index, bilirubin, sulfhemoglobin, red blood cell scattering and nonspecific scattering vectors, the same reasoning cited above applies. It is up to the person conducting the measurement, as to what specifics are required for that specific outcome to occur.

In regard to claims 12-15, see page 177, second to last line of the first paragraph.

RES JUDICATA

Claims 1-2, 5-6, 9-21, 23-24, 26-27, and 29-36, 37, 41-43 (as understood by Examiner) are rejected under Res Judicata on the basis of an earlier adverse decision of the board of Appeals against the inventor on the same claim or a claim involving the same (See MPEP 706.03(w)).

REJECTION III

103 REJECTION

Claims 1, 10, 20-24, 26-27, and 34-36, 37, 41, 43 (as understood by Examiner) are rejected under 35 U.S.C. § 103 as being unpatentable over Anderson et al. in view of Brown et al.

Anderson, in a whole unaltered blood measuring system, disclose everything except is vague as to the following:

A) measurements at different wavelengths to calculate several different constituents of blood.

Brown, in a blood measuring system, disclose item A above.

At the time the invention was made, it would have been obvious to one with ordinary skill in the art to modify Anderson to incorporate item A of Brown.

The rationale for this modification would have arisen for the following reason. It would have been apparent to incorporate item A of Brown in Anderson since Anderson suggests data-gathering at appropriate wavelengths to calculate three or more constituents of blood as seen on page 182, section 4.2 and it is well known to calculate several different constituents of blood at different wavelengths to provide specific data of interest as seen and taught by Brown.

103 REJECTION

Claims 2-9, 11-19, 25 and 28-33, 38-40, 42, 44 (as understood by Examiner) are rejected under 35 U.S.C. § 103 as being unpatentable over Anderson-Brown.

The Anderson-Brown system fails to disclose the specific depth of the sample, the specific detecting area, the specific distance from the sample, the specific half aperture angle of radiation emanating from the sample, computing an error index, selecting a wavelength range for bilirubin of sulfhemoglobin, red blood cell scattering vector and non specific scattering vector.

At the time the invention was made, it would have been obvious to one with ordinary skill in the art to modify the Anderson-Brown system to incorporate the specifics cited above. The rationale for this modification would have arisen, since it is apparent that the depth of the sample, the detecting area, the distance from the sample, and the half aperture angle all have a specific effect on the overall-measurement and it is a matter of design engineering to select which depth, area distance, or angle is required for a particular outcome. Anderson specifically shows that for different depths, different wavelengths etc., different results occur. Thus, a specific relationship between all of the specifics cited above are well known and it is up to the person conducting the measurement what specifies are required for that specific outcome to occur. As for the error index, bilirubin, sulfhemoglobin, red blood cell scattering and non

specific scattering vectors, the same reasoning cited above applies. It is up to the person conducting the measurement, as to what specifics are required for that specific outcome to occur.

In regard to claims 12-15, see page 177, second to last line of the first paragraph.

Also, in regard to HbO_2,Hbco etc and their error index; see columns 3-4 of Brown where specific calculations show changes in optical densities and the molar extinction coefficients are derived so as to obtain the concentrations of four hemoglobin species.

In regard to claims 16-17; 31 Brown discloses that it is well known to measure for bilirubin from specific wavelength measurement - See column 1, lines 25+. From this teaching claims 18-19, 32-33 are apparent.

REJECTION IV

103 REJECTION

Claims 1, 10, 20-24, 26-27, and 34-36, 37, 41, 43 (as understood by Examiner) are rejected under 35 U.S.C. § 103 as being unpatentable over Anderson et al. in view of Brown et al.

Anderson, in a whole unaltered blood measuring system, disclose everything except is vague as to the following:

A) measurements at different wavelengths to calculate several different constituents of blood.

Brown, in a blood measuring system, disclose item A above.

At the time the invention was made, it would have been obvious to one with ordinary skill in the art to modify Anderson to incorporate item A of Brown.

The rationale for this modification would have arisen for the following reason. It would have been apparent to incorporate item A of Brown in Anderson since Anderson suggests data-gathering at appropriate wavelengths to calculate three or more constituents of blood as seen on page 182, section 4.2 and it is well known to calculate several different constituents of blood at different wavelengths to provide specific data of inherent as seen and taught by Brown.

103 REJECTION

Claims 2-9, 11-19, 25 and 28-33, 38-40, 42, 44 (as understood by Examiner) are rejected under 35 U.S.C. § 103 as being unpatentable over Anderson-Brown.

The Anderson-Brown system fails to disclose the specific depth of the sample, the specific detecting area, the specific distance from the sample, the specific half aperture angle of radiation emanating from the sample, computing an error index,

selecting a wavelength range for bilirubin or sulfhemoglobin, red blood cell scattering vector and non specific scattering vector.

At the time the invention was made, it would have been obvious to one with ordinary skill in the art to modify the Anderson-Brown system to incorporate the specifics cited above. The rationale for this modification would have arisen, since it is apparent that the depth of the sample, the detecting area, the distance from the sample, and the half aperture angle all have a specific effect on the overall-measurement and it is a matter of design engineering to select which depth, area distance, or angle is required for a particular outcome. Anderson specifically shows that for different depths, different wavelengths etc., different results occur. Thus, a specific relationship between all of the specifics cited above are well known and it is up to the person conducting the measuring what specifies are required for that specific outcome to occur. As for the error index, bilirubin, sulfhemoglobin, red blood cell scattering and non specific scattering vectors, the same reasoning cited above applies. It is up to the person conducting the measurement, as to what specifics are required for that specific outcome to occur.

In regard to claims 12-15, see page 177, second to last line of the first paragraph.

Also, in regard to Hbo_2, Hbco etc and their error index; see columns 3-4 of Brown where specific calculations show changes in

optical densities and the molar extinction coefficients are derived so as to obtain the concentrations of four hemoglobin species.

In regard to claims 16-17; 31 Brown discloses that it is well known to measure for bilirubin from specific wavelength measurement - See column 1, lines 25+. From this teaching claims 18-19, 32-33 are apparent.

RES JUDICATA

Claims 1-2, 5-6, 9-21, 23-24, 26-27, and 29-36, 37, 41-43 (as understood by Examiner) are rejected under Res Judicata on the basis of an earlier adverse decision of the board of Appeals against the inventor on the same claim or a claim involving the same issue (See MPEP 706.03(w)).

RESPONSE TO APPLICANT'S REMARKS OF AMENDMENT OCTOBER 12, 1995---
Applicant's remarks are cited as A1-7B of the amendment above and have been responded to using these item representations---

Examiner's Response to Applicant's A1

Applicant's argues that "it is not and never has been the law" to have literal correspondence between the claims and specification.

I. The Examiner never recited that it was "law" to secure correspondence. 37 CFR 1.117 cites "the specification, claims and drawings must be amended and revised when required to correct for inaccuracies of description and definition or unnecessary prolixity and to secure correspondence between the claims, the specification and the drawing. Therefore, this objection was is valid.

Examiner's Response to Applicant's items A2-A3

Applicant cites the original specification at page 20, lines 24-29 and then interprets this recitation; i.e. "In other words ... wavelengths".

The original recitation of page 20, lines 24-29 is broad and does not specifically recite some of Applicant's interpretation,

therefore, new matter has been added (see new matter rejection above).

Also, the original specification claims and drawings do not recite the numbers; 5 wavelength being absorbance, subset 2 wavelength being absorbance subsets; 2 wavelength being scattering subsets. In fact the original claims recite "plurality" which can include any number.

Applicant specifically recites on page 13, lines 7-13 of Amendment and Response of October 12, 1995 "although the original specification (other than the original claims) never used the subset terminology the original specification provided clear support for the generation of a plurality of wavelengths including an absorbance subset of wavelengths and a scattering subset of wavelengths".

To further prosecution of this case the further definition of absorbance subset and scattering subset of the specific wavelengths is not disputed, but the number 5/2 and n, k, n-k definitions inserted in November 11, 1996 in the original specification claims and drawings.

The original specification claims and drawings recite broadly that a plurality of wavelengths are assigned absorbance subsets/scattering subsets. The exact number and assigning of n, k, n-k is not found anywhere in the original specification, claims and drawings, therefore, the new matter rejection of this office action is proper.

Examiner's Response to Applicant's item B

Applicant argues that the radiation wavelengths are selected to maximize absorbance, minimize scattering and some are selected to maximize scattering relative to absorbance.

First Applicant's reminded of what claim 1 recites, for example.

Lines 3-7 recite the following:

A) each wavelength of an absorbance subset of said plurality of wavelengths selected to minimize the effects of radiation scattering.

Lines 7-9 recite the following:

B) each wavelength of a scattering subset of said plurality of wavelengths having been selected to maximize the effects of radiation scattering.

Lines 11-13 recite the following:

C) irradiating a sample of unaltered whole blood of unknown composition with said plurality of radiation wavelengths through a depth of said sample to minimize radiation scattering by unaltered whole blood

Lines 14-17 recite the following:

D) detecting intensities of said radiation wavelengths after passing through said depth of said sample at a distance from said

sample and over a detecting area, both chosen to minimize the effects of radiation scattering.

Lines 14-17 recites that said plurality of radiation wavelengths are irradiated to minimize the radiation scattering. It is not recited in the claim that there plurality of radiation wavelengths are some wavelengths selected to maximize scattering relative to absorbance.

Claim 1 recites that the plurality of wavelength have an absorbance subset and a scattering subset and a scattering subset (lines 3-7, 7-9). It does not recite that the plurality of wavelengths of lines 14-17 are different from the absorbance subset or scattering subset as Applicant appears to be arguing.

In fact, claim 1 reads that the plurality of wavelengths include the absorbance subset and scattering subset.

Therefore the 112 rejection, second paragraph of the last office action still stands.

Examiner's Response to item C

I) Declaration of Joseph M. Schmitt under 37 CFR 1.132 signed Feb. 25, 1994

II) Declaration of Roland N. Pittman

Under 37 CFR 1.132 signed Feb. 28, 1994

Examiner's Response to Declarations I-II

As already considered in the Office Action of April 26, 1995:

The Declaration of Schmitt and Pittman under 37 CFR 1.132 have been entered considered but deemed mute since they argue that the curve-fitting techniques of Anderson are different from Applicant's device where these differences of techniques are not claimed in Applicant's claims. Also deemed mute to the new rejection reference to Brown.

III) Declaration of Gert E. Nilsson under 37 CFR 1.132 signed Dec. 8, 1994.

IV) Declaration of Per Ake Oberg under 37 CFR 1.132 signed Dec. 12, 1994.

Examiner's Response to Declarations III-IV

As already considered in the Office Action of April 26, 1995:

The Declarations of Mr. Nilsson and Mr. Oberg under 37 CFR 1.1132 have been considered, but deemed mute due to the rejections in reference to Brown.

V) Supplemental Declaration of Joseph M. Schmitt under 37 CFR 1.132 signed July 10, 1995.

A) Mr. Schmitt argues that Anderson measures altered whole blood of known composition in that the blood is altered by Anderson separating the red blood cells from other components of whole blood.

Anderson states on page 173-174 that the purpose of the present study was to investigate the light-scattering and light absorbing properties of nonhaemolyged blood, i.e. unaltered whole blood.

Anderson then continues to compare the haemoglobin i.e. altered blood to the nonhaemolysed blood (unaltered whole blood) on pages 174, and 177-183. From Applicant's citation of page 177 and reading the Anderson as a whole, it appears that Applicant's citation is in reference to the hemolyzed blood that is used to compare with measurements of the nonhaemolysed blood.

Since the whole reference of Anderson is directed to measuring unaltered whole blood and comparing these results to the old art of measuring altered blood, clearly Applicant's arguments that Anderson is measuring only hemolyzed blood is mute.

B) Mr. Schmitt argues that the sample of blood tested by Anderson is not unknown since Applicant refers to page 177 again

where the citation states fully oxygenated nonhaemolysed red cells suspended in isotonic saline. Applicant argues that the cells are fully oxygenated, therefore it is known what composition is in the samples of blood.

First, the Examiner does not agree that this recitation is the only sample measured in Anderson's system. This sample appears to be the comparison sample and not the main samples measured. The comparison sample being altered blood being compared to Anderson's improvement over the prior art - the measuring of whole unaltered blood.

Second, Anderson does measure a known composition of whole unaltered blood and then creates a graph. This gives a calibration curve. Then, Anderson evaluates whole unaltered blood of unknown composition and compares this to the calibration curve.

Anderson, also, compares hemolyzed (altered) and nonhaemoalyzed (unaltered) samples (see page 178). Therefore, Anderson does measure the unknown composition of whole unaltered blood.

Also, note on page 178, under 3.3 that both types of blood - hemolyzed (altered) and nonhaemolysed (unaltered) were measured and compared.

C) Mr. Schmitt argues that Anderson that the correction method suggested by the Examiner would completely fail.

It is unclear what Mr. Schmitt appears to believe the Examiner's correction method is. The rejection of Anderson in the Office Action merely states that Anderson must have a correction or else Anderson's results would be meaningless. Also, note that none of the claims use Mr. Schmitts phraseology as cited in items 8-14 of this Declaration; specifically item 14, lines 6-8.

Also, Applicant's does attest to Anderson having a correction in line 21 of page 14 of Applicant's Remarks of Dec. 20, 1994.

D) Mr. Schmitt argues that Brown requires hemolysis and dilution of whole blood and uses only scattering correction by hemolyzing the blood.

As Anderson teaches that the basic disclosed arrangement is able to make the same absorption measurements on whole non-hemolyzed blood, it would have been obvious to make the same tests as taught by Brown et al, using the same wavelengths as taught by Brown, for the purpose of determining constituents as taught Brown and a suggested by Anderson both by the disclosed connection to "conventional spectrophotometric techniques" and by the determination of oxygen saturation, which is a determination

of a "constituent component" of the blood, using wavelengths which are disclosed by Anderson as being in the region when the relationship between measurements on hemolyzed and non-hemolyzed blood is linear.

As to the Brown reference it is noted that Brown discloses the measurement of "whole blood"; see the abstract, third line; column 2, lines 22-28; column 10, line 9; column 11, line 39; and column 13, lines 27, 42 and 45. See also claim 9, line 3; claim 11, line 2; and claim 14, line 2. Instant claim 1 also calls for measuring "whole blood". Thus much of the argued distinction between the blood tested by Brown and that of the instant claims is in fact not present in the instant claims; both measure "whole blood"; Brown not only suggests, but teaches and claims using "whole blood."

Brown does not mention the Anderson data and clearly does not "specifically avoid" using it. Brown uses wavelengths three of which are within the disclosed linear relationship between hemolyzed blood and non-hemolyzed (unaltered) blood of Anderson (section 3.3) and the fourth (626.6nm) in just outside the disclosed range (which goes to 620nm). Thus it is clear that Brown is consistent with the teachings of Anderson in using wavelengths generally taught by Anderson as being useful both with the non-hemolyzed (unaltered blood of Anderson and the hemolyzed blood of "conventional" techniques and generally within the teachings of Anderson as being within the range in which

equivalence between the two methods is explicitly disclosed; i.e., where the relationship is linear.

Anderson's teachings clearly include the concept that frequencies of radiation for use in analyzing whole undiluted unaltered blood should be selected such that scattering is minimized and absorption is maximized. Anderson also teaches that a thin or reduced depth sample is needed to further reduce scattering and that all radiation from the sample, or at least as much as possible, should be collected for detection.

Brown's teachings, to be considered with those of Anderson, relate to the advantageous use of plural detecting frequencies and equations to enable the detection of constituent hemoglobin components under a Beer-Lambert style analysis, i.e where absorption is dominant and scattering effects have been reduced. It is manifest that Brown uses hemolyzed blood to insure sufficient absorption and reduced scattering effects for this analysis to be valid. However, this does not mean that the teachings of Anderson (as to using a greatly reduced depth of the sample and a wide range detector to collect as much radiation, even scattered radiation, as possible along with the use of radiation analyzing frequencies of minimal scattering effect (dominant absorption and high extinction coefficients) to analyze, at least in part, the constituents of nonhaemolysed (unaltered) blood would not have been meaningful to those skilled in the art.

The artisan must be presumed to have been of sufficient skill to have recognized the clear advantage and relative simplicity of blood handling associated with the Anderson use of undiluted unaltered blood compared to the complexities of preparation and handling associated with the diluted blood required by Brown. It is also of the view that this same artisan would not have ignored the teachings of Brown as to clear advantageous solving for plural component constituents with plural frequencies. In this respect, it is well settled that the artisan is presumed to be able and motivated, by at least common sense, to optimize known result dependent variables, such as the selection of these plural frequencies, so that the Anderson requirement of high extinction coefficients (low scattering, high absorption) would have been met.

E) Mr. Schmitt argues that Curtis does not analyze unaltered blood and cited col. 2, lines 4-6 and col. 5, lines 45-52. The Curtis Rejection is withdrawn.

F) Mr. Schmitt argues that Curtis does not distinguish the absorbance subset from the scattering subset. The Curtis rejection is withdrawn.

G) Mr. Schmitt argues that Curtis does not maximize the effects of radiation scattering by unaltered whole blood relative to the effects of radiation absorbance by unaltered whole blood.

The Curtis rejection is withdrawn.

VI) Declaration of A.P. Shepard under 37 CFR 1.132 signed Dec. 12, 1994.

The Declaration of Shepherd, under 37 CFR 1.132 has been considered but deemed mute since it has given little evidentiary value because it is not clear what the commercial success is attributed to because of the indefinite language used. Under 4. it states "the elements of at least Claim I." What else does it embody? Under 7 it states that technology disclosed and claimed and Exhibit B states Mr. Mountain has not seen a copy of the claims. It is not clear what the License agreement covers.

VII) Declaration of Charles F. Mountain under 37 CFR 1.132 signed July 6, 1995.

A) Mr. Mountain generally argues that his Brown Patent 4134678 cannot be used in combination with Anderson.

Applicant is directed to Part D of the Examiner's Response of the V. Declaration of Shcmitt above.

Also, note that no factual support is evidenced.

Also, this declaration has little weight when considered in light of all the evidence of record in the instant application.

VIII) Declaration of Thomas Scecina under 37 CFR 1.132 signed July 13, 1995.

A) Mr. Scecina generally argues the need and accuracy of measuring unaltered whole blood.

No factual support is evidenced. This declaration has little weight when considered in light of all the evidence of record in the instant application.

IX) Supplemental Declaration of A.P. Shepherd under 37 CFR 1.131 signed August 14, 1995.

A) Item 9 recites that neither our system that existed prior to Sept. 26, 1989 nor our Patent Application Serial No. 07/313919 embodied or disclosed the use of a scattering subset of wavelengths used to correct the calculations of the concentrations of hemoglobin species for the effects of radiation scattering in unaltered whole blood.
The Curtis rejection is withdrawn.

B) Mr. Shepherd and Steinke in item 9 recite that Curtis does not disclose the phraseology cited in item A of IX above.

The Curtis rejection is withdrawn.

X) Supplemental Declaration of A.P. Shepherd under 37 CFR 1.132 signed Aug. 1995.

A) the gross sales figures do not show commercial success absent evidence as to market share

B) item 2 recites that the Examiner is unreasonable to imply that the product has unclaimed functions that would somehow contribute to the commercial success of the product

It is not unreasonable for the Examiner to imply the product had unclaimed functions that would contribute to the commercial success of the product since no evidence has been shown to support that only the claimed features are what is enabling the commercial success.

The presence of the Examiner at the demonstration is mute.

It is not shown that claimed features of the instant application were responsible for the commercial success of the Avox-1000; part 5 of the Declaration recites that the cash receivables totalling 261,513 were for the oximeter AND disposable cuvettes used with the oximeter.

There is no evidence that the reason for the license is due to the claimed features of the instant application.

Examiner's Response to item 2a

A) See Examiner's Response to X Supplemental Declaration of AP Shepherd under 37 CFR 1.132 signed Aug. 1995.

B) Applicant recites on page 21, lines 4-8 of the Amendment of Nov. 11, 1995 that "Facts established by rebuttal evidence must be evaluated along with facts on which the earlier conclusion of obviousness is reached, not against the conclusion itself. In other words, it is error to review rebuttal evidence solely for its "knockdown ability".

Again there is no evidence or "facts" showing that the claimed features of the instant application are responsible for the commercial success.

Merely showing that there was commercial success of an article which embodied the invents is not sufficient.

Licensing programs may succeed for reasons unrelated to the unobviousness of the product or process e.g. License is mutably beneficial or less expensive then defending infringements.

Applicant's argues that a nexus has been established between the commercialization of the present invention and the claimed invention because at least claim 1 of the present invention application covers the entire Avoximeter 1000 and because the licensed technology is the very technology described in the subject patent application.

There is no evidence to support a factual and legally sufficient connection between the evidence of commercial success and the claimed invention. The commercial success may have been attributed to extensive advertizing and position as a market leader before the introduction of the product success may be attributed to related technology; consumer demand.

Examiner's Response to 2B

Table IV on page 40 of the specification merely shows to comparison of hemolyzed blood results with nonhemolized (unaltered blood) results. Each gentleman (Mr. Mountain, Mr. Sceina) find the invention to produce remarkable and surprising results. There is no evidence to support that these results are due only to the claimed features.

Table IV is a comparison of end results not a comparison of the claimed features of the instant Application.

Opinion evidence praising the merits of the claimed invention have little value because of a lack of factual support.

Applicant argues that a long felt need is showed by Mr. Mountain and Mr. Sciena declarations.

Again there is no objective evidence to support that the problem of hemolyzing blood existing in the art for a long period of time.

There is no objective evidence to support if this need is a persistent one.

Second the Anderson reference do support the measuring of unaltered blood.

Examiners' Response to item 3a

A) Mr. Schmitt argues that Anderson measures altered whole blood of known composition in that the blood is altered by Anderson separating the red blood cells from other components of whole blood.

Anderson states on page 173-174 that the purpose of the present study was to investigate the light-scattering and light absorbing properties of nonhaemolyged blood, i.e. unaltered whole blood.

Anderson then continues to compare the haemoglobin i.e. altered, diluted blood to the nonhaemolysed blood (unaltered/ whole blood) on pages 174, and 177-183. From Applicant's citation of page 177 and reading the Anderson as a whole, it appears that Applicant's citation is in reference to the hemolyzed blood that is used to compare with measurements of the nonhaemolysed blood.

Since the whole reference of Anderson is directed to measuring unaltered whole blood and comparing these results to the old art of measuring altered blood, clearly Applicant's

arguments that Anderson is measuring only hemolyzed blood is mute.

Applicant argues that the sample of blood tested by Anderson is not unknown since Applicant refers to page 177 again where the citation states fully oxygenated nonhaemolysed red cells suspended in isotonic saline. Applicant argues that the cells are fully oxygenated, therefore it is known what composition is in the samples of blood.

First, the Examiner does not agree that this recitation is the only sample measured in Anderson's system. This sample appears to be the comparison sample and not the main samples measured. The comparison sample being altered blood being compared to Anderson's improvement over the prior art - the measuring of whole unaltered blood.

Second, Anderson does measure a known composition of whole unaltered blood and then creates a graph. This gives a calibration curve. Then, Anderson evaluates whole unaltered blood of unknown composition and compares this to the calibration curve.

Anderson, also, compares hemolyzed (altered) and nonhaemoalyzed (unaltered) samples (see page 178). Therefore, Anderson does measure the unknown composition of whole unaltered blood.

Also, note on page 178, under 3.3 that both types of blood - hemolyzed (altered) and nonhaemolysed (unaltered) were measured and compared.

Examiner's Response to Applicant's item 3b

See Examiners' Response to Applicant's item 3a.

Also page 29, lines 1-7 of Applicant (10/12/95) recite that Anderson do not and in fact is incapable of making meaningful measurement of the concentrations of constituent components of unaltered whole blood because Anderson do not adequately take into account any of the scattering factors present in unaltered whole blood. This statement recites that Anderson does indeed make measurements of concentrations of unaltered whole blood and does take into account scattering factors but that these accounts are not satisfactory as to Applicant. The claims do not recite the accuracy of the results as Applicant appears to be arguing above. Also, Anderson is making measurement of concentrations and does take into account scattering facts as evidence on pages 173-176.

Examiner's Response to Applicant's item 3c

Anderson must have a correction or else Anderson's result would be meaningless. Also note that none of the claims use

Applicant's phraseology as cited on pages 35, 6-24 of Applicant's Remarks of Oct. 12, 1995. Also Applicant's do attest to Anderson having a correction in line 21 of page 14 of Applicant's Remarks of Dec. 20, 1994.

Examiner's Response to Applicant's item 4a-c

The Curtis rejection is withdrawn.

Examiner's Response to Applicant's item 5a-c

See Examiner's Response to Declarations Supplemental Declaration of Joseph M. Schmitt under 37 CFR 1.132 signed July 10, 1995 and Declaration 37 CFR 1.132 of Mr. Mountain signed July 6, 1995.

Examiner's Response to Applicant's item 6a-d

Due to the 112 first paragraph new matter rejections the 112 second paragraph rejection; The difference is foggy, despite the chart on page 47 of Applicant's response of 10/1295. Therefore the same rejections of the last office action have been repeated to incorporate this difference or to incorporate no difference.

Examiner's Response to Applicant's item 7a-b

See 112 first/second paragraph rejections plus the art rejections.

APPLICANT'S ARGUMENTS CONSIDERED

Applicant's arguments filed Oct. 12, 1995 have been fully considered but they are not deemed to be persuasive.

ACTION FINAL

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication should be directed to K. Hantis at telephone number (703) 308-4801.

K. Hantis

Hantis/tj

Feb. 21, 1996

K. HANTIS
PATENT EXAMINER
ART UNIT 2505